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Date of mailing *(day/month/year)* 25. 01. 2005

International application No.
PCT/EP2004/014572

The receiving Office transmits herewith the following documents:

1. ☐ the record copy (Article 12(1)) (only for the IB).
2. ☐ the search copy of form PCT/RO/101 (Article 12(1)) (only for the ISA).
3. ☐ the confirmation copy (Administrative Instructions, Section 331) (only for the IB).
4. ☐ substitute sheets (Administrative Instructions, Section 325(a)).
5. ☐ later submitted sheets (Administrative Instructions, Section 309(b)(iii), (c)(ii)).
6. ☐ later submitted drawings (Administrative Instructions, Section 310(c)(iii), (d)(ii)).
7. other document(s):

- ☒ letter(s) dated: 04-01-2005.
- ☐ ____ power(s) of attorney (only for the IB).
- ☐ statement(s) explaining lack of signature considered to be satisfactory by this receiving Office (only for the IB).
- ☒ 1 priority document(s) (only for the IB).
- ☐ fee calculation sheet (only for the IB).
- ☐ document(s) concerning deposited biological material.
- ☐ nucleotide and/or amino acid sequence listing(s) in computer readable form (only for the ISA).
- ☐ PCT EASY diskette (only for the IB).
- ☐ earlier search(es) (only for the ISA).
- ☐ Form PCT/RO/106.
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59
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To avoid unnecessary delay, please quote our reference!

Your Ref : PCT/EP2004/014572
Our Ref : P66637PC00/MOC/BON/ls

By Courier

January 4, 2005

REC'D 26 JAN 2005
WIPO PCT

Dear Sirs,

International Application No. PCT/EP2004/014572
"An Anti Reflux System"
Patrick Leahy

Please now find enclosed the priority document for the above application.

Form 1037 is enclosed.

Yours faithfully

Brian O'Neill
Representative

Encls.

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PCT/EP2004/014572

10 JAN 2005

Patents Office
Government Buildings
Hebron Road
Kilkenny

I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	S2003/0954
Date of Filing	19 December 2003
Applicant	MR PATRICK LEAHY, an Irish citizen of The Laser Centre, 14 Hume Street, Dublin 2

Dated this 22 day of December 2004.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

FORM NO. 1

S030954 L5030

REQUEST FOR THE GRANT OF A PATENT
PATENTS ACT, 1992

The Applicant named herein hereby request

☐ the grant of a patent under Part II of the Act

☒ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. **APPLICANT(S)**
Name(s) and Address(s) **Mr Patrick Leahy**
The Laser Centre
14 Hume Street
Dublin 2

DescriptionNationality: An Irish Citizen

2. **TITLE OF INVENTION**

"An Anti Reflux device"

3. **DECLARATION OF PRIORITY ON BASIS OF PREVIOUSLY FILED APPLICATION FOR SAME INVENTION (SECTIONS 25 & 26)**

Previous filing date	Country in or for which filed	Filing No.
NONE		

4. **IDENTIFICATION OF INVENTOR(S)**
Name(s)/Address(es) and Nationality of person(s) believed by Applicant(s) to be the inventor(s)

Mr Patrick Leahy
The Laser Centre
14 Hume Street
Dublin 2

An Irish Citizen

5. **STATEMENT OF RIGHT TO BE GRANTED A PATENT (SECTION 17(2)(B))**
By virtue of the applicant being the inventor.

6. **ITEMS ACCOMPANYING THIS REQUEST - TICK AS APPROPRIATE**

(i)	☒	prescribed filing fee (€60.00)
(ii)	☐	specification containing a description and claims
	☒	specification containing a description only
	☒	Drawings referred to in description or claims
(iii)	☐	An abstract
(iv)	☐	Copy of previous application(s) whose priority is claimed
(v)	☐	Translation of previous application whose priority is claimed
(vi)	☐	Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. **DIVISIONAL APPLICATION**

The following information is applicable to the present application which is made under Section 24 -

Earlier Application No:
Filing Date:

8. **AGENT**

The following is authorised to act as agent in all proceedings connected with the obtaining of a Patent to which this request relates and in relation to any patent granted -

Name	**Address**
F. R. KELLY & CO.	at their address as recorded for the time being in the Register of Patent Agents

9. **ADDRESS FOR SERVICE (IF DIFFERENT FROM THAT AT 8)**

Patrick Leahy
F. R. KELLY & CO.

By: _____
EXECUTIVE

Date: December 19, 2003

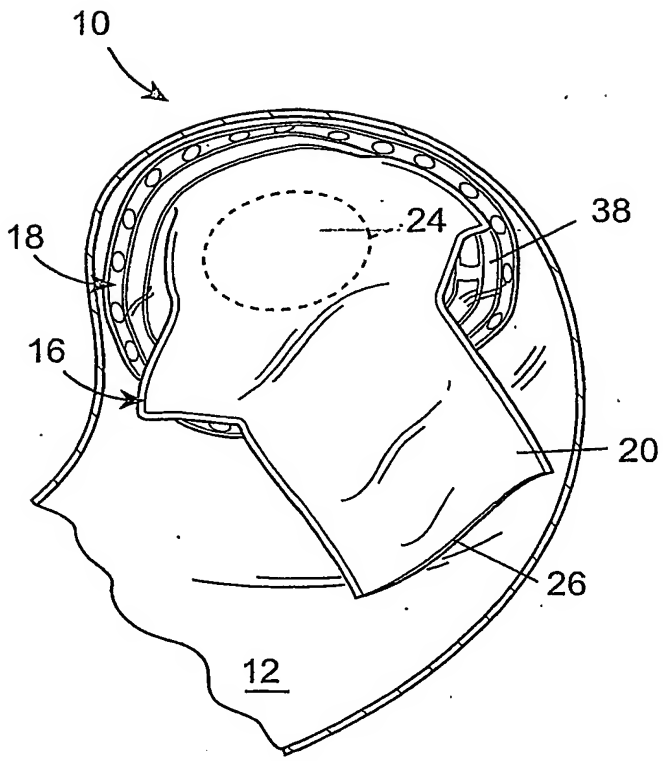

Fig. 1

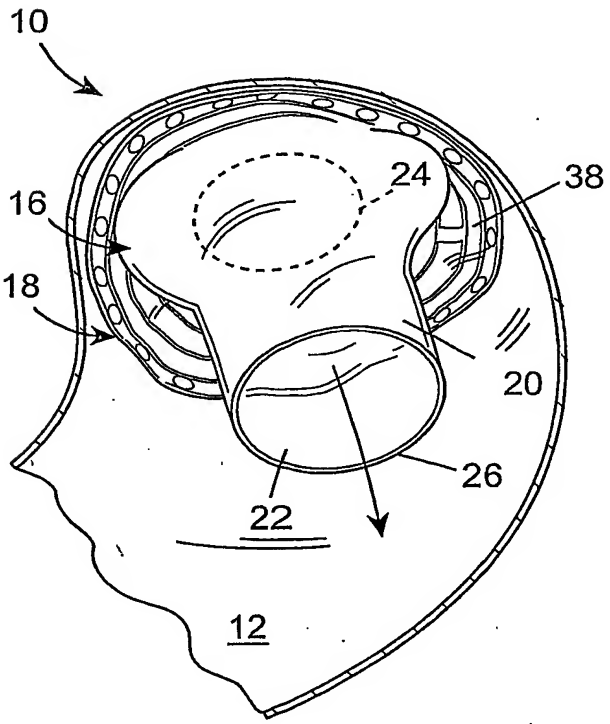

Fig. 2

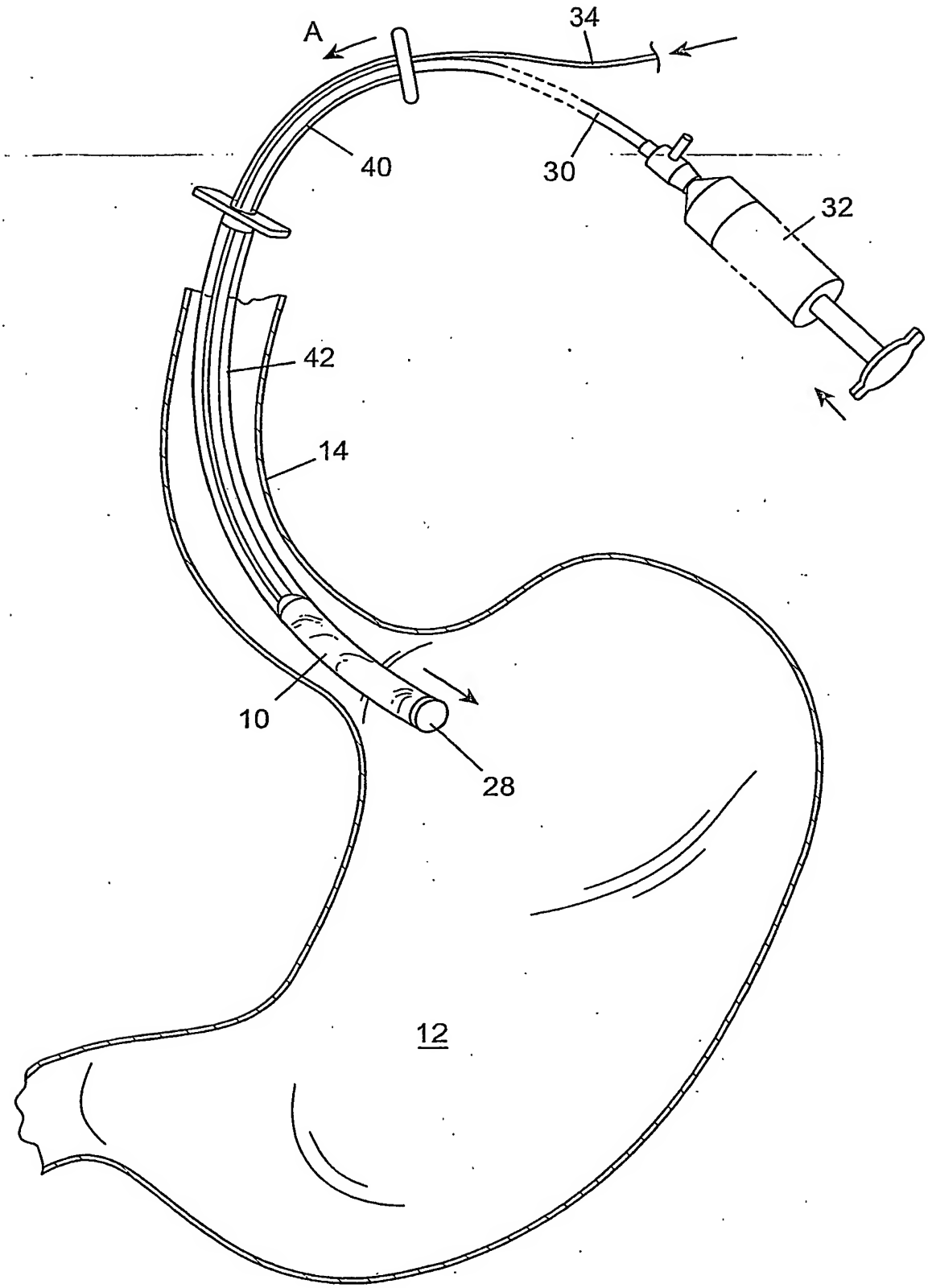

Fig. 3

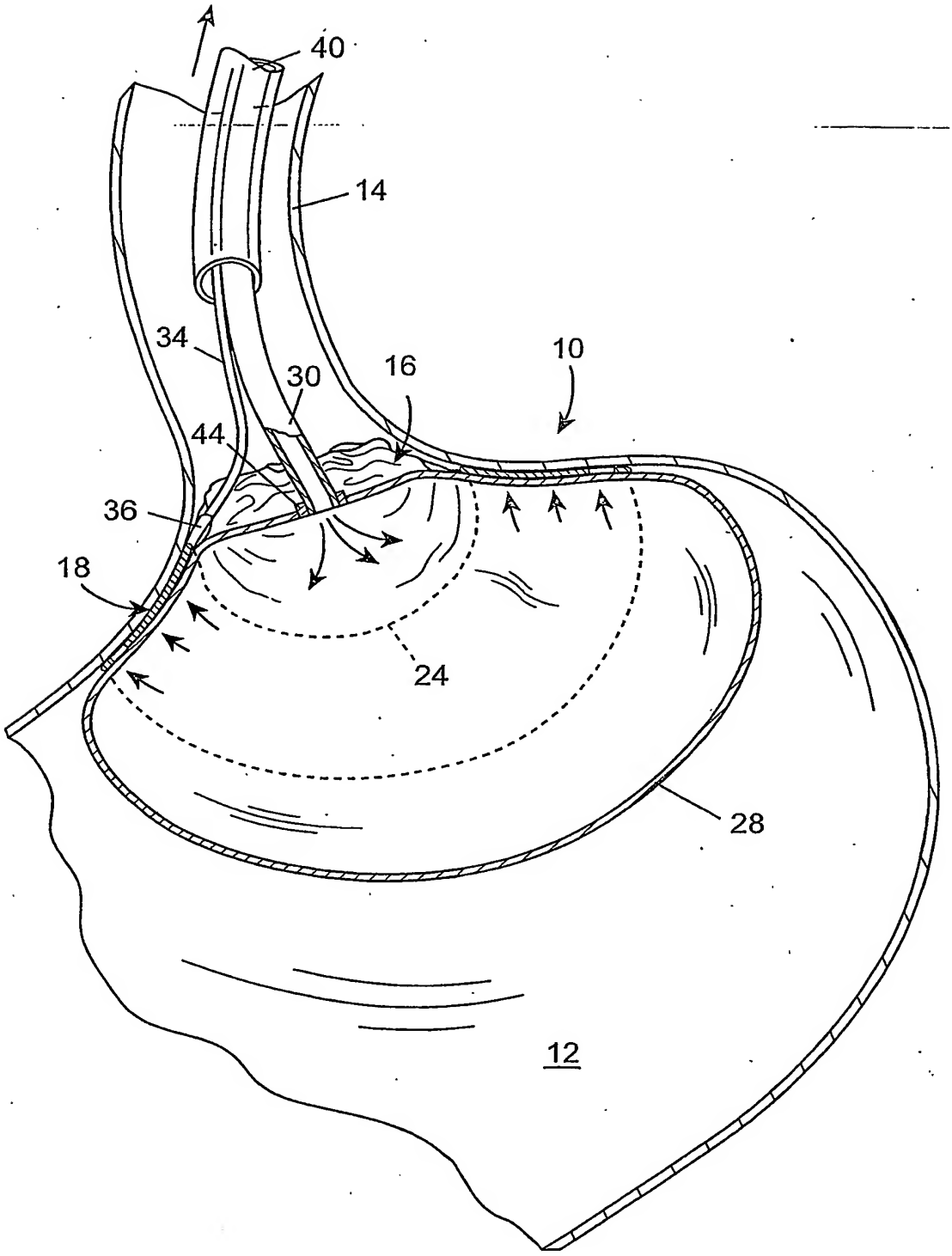

Fig. 4

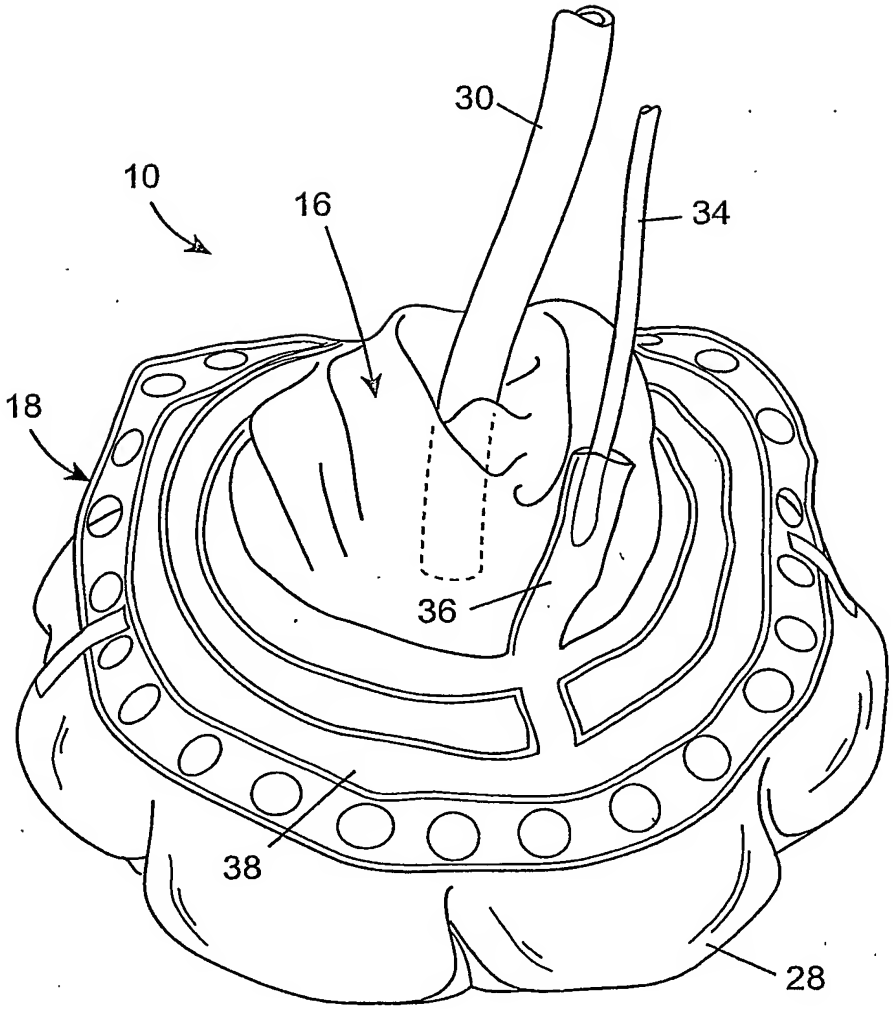

Fig. 5

An Anti-Reflux Device

The present invention is concerned with an anti re-flux device, and in particular an anti re-flux device for location at the entrance to the stomach, adjacent the lower oesophageal sphincter muscle.

At some stage almost every person will experience indigestion or heartburn to some degree. Gastroesophageal reflux, the medical name for heartburn, is the condition in which stomach acid is regurgitated into the oesophagus, resulting in the burning sensation that can radiate into the throat. However, in a large number of individuals, gastroesophageal reflux is sufficiently frequent or severe such as to cause more significant problems, and is considered to be a disease, known as gastroesphageal reflux disease (GERD).

This disease occurs when the lower oesophageal sphincter muscle ceases to function normally, and for example is either weak or relaxes inappropriately when exposed to certain stimuli, such as particular food types, alcohol, exercise, or certain types of medication. GERD damages the lining of the oesophagus, resulting in considerable pain and inflammation. During the day, such reflux is significantly less damaging, as the oesophagus is protected by swallowing, saliva and the effect of gravity tending to cause the stomach acid to drain back into the stomach. However, while lying asleep at night, the effectiveness of the

aforementioned protective mechanisms are significantly reduced, and thus stomach acid is likely to remain in the oesophagus for prolonged periods, causing greater damage.

The present invention therefore seeks to provide an anti reflux device which effectively replaces the lower oesophageal sphincter muscle, in order to prevent gastroesophageal reflux. The present invention further seeks to provide an anti reflux device which may remain operational for a prolonged period, in order to allow the lower oesophageal sphincter muscle to naturally repair.

The present invention therefore provides an anti reflux device comprising a flange which is adapted to be secured to a wall of the stomach; and a valve secured to the flange, the valve permitting, during normal operation, unidirectional flow from the oesophagus into the stomach.

Preferably, the valve is a mitral valve.

Preferably, the flange is provided, in use, with an adhesive in order to secure the device to the stomach wall.

Preferably, the device is formed from a biodegradeable material.

Preferably, the device is provided with a detachable balloon operable to press the flange against the stomach wall.

Preferably, the direction of flow of the valve may be reversed when a pre-determined threshold pressure is reached within the stomach.

According to a second aspect of the present invention, there is provided a method of inserting an anti reflux device according to the first aspect of the invention, the method comprising passing the device, in a collapsed state, down the oesophagus; unfurling the device; and pressing the flange against the stomach wall in order to adhere the device to the stomach wall.

Preferably, the method comprises wrapping the device around a deflated balloon prior to passage down the oesophagus; inflating the balloon in order to unfurl the device; and drawing the balloon against the stomach wall in order to adhere the device to the stomach wall.

Preferably, the method comprises applying an adhesive to the flange prior to pressing the flange against the stomach wall.

Preferably, the method comprises pumping the adhesive onto the flange from outside the stomach.

Preferably, the method comprises allowing the balloon to drop into the stomach once the device has been adhered to the stomach wall.

The present invention will now be described with reference to the accompanying drawings, in which;

Figure 1 illustrates a perspective view of an anti reflux device according to the present invention, in a closed state, secured to a wall of the stomach;

Figure 2 illustrates the anti reflux device of Figure 1, in an open state, allowing passage into the stomach;

Figure 3 illustrates a perspective view of the anti reflux device, in a collapsed state, being passed down the oesophagus and into the stomach;

Figure 4 illustrates the anti reflux device being pressed against the stomach wall by a balloon inflated adjacent thereto; and

Figure 5 illustrates a perspective view of the anti reflux device of the invention, in isolation from the stomach, with the balloon deflated therebeneath.

Referring now to the accompanying drawings, there is illustrated an anti reflux device, generally indicated as 10, which, in use, prevents the reflux of stomach acid, in particular where the lower oesophageal sphincter muscle has ceased to function correctly. The

device 10 is located, in use, in a stomach 12 of a patient (not shown), at the entrance from an oesophagus 14. The device 10 is therefore seated adjacent the lower oesophageal sphincter muscle (not shown), and supersedes the operation of same while the device 10 is in place. The device 10 is preferably formed from a flexible biodegradeable material, which can be designed to biodegrade after a pre-determined period, for example 6 to 12 months. The working life of the device 10 is preferably chosen to suit the needs of the individual patient, in particular the length of time expected for the damaged lower oesophageal sphincter muscle to repair, whether naturally or with the aid of suitable medication or surgery.

The device 10 essentially comprises a valve 16 depending from a flange 18, which flange 18 is adapted to be adhered to the stomach 12, as will be described in greater detail hereinafter. The valve 16 is adapted to permit unidirectional flow from the oesophagus 14 into the stomach 12 and to prevent the reflux of stomach acid into the oesophagus 14. In the preferred embodiment illustrated, the valve 16 is a mitral valve, although it will be appreciated that any other suitable equivalent may be used in place thereof. However, the configuration of the valve 16 gives simple yet highly effective operation, in addition to allowing reversal of flow therethrough upon a threshold pressure being reached within the stomach 12, for example during vomiting, as will be described hereinafter.

The valve 16 comprises a first side 20 and a second side 22, formed from a flexible material such as plastic or the like, each of which sides 20, 22 is sealed to the flange 18, about a central aperture 24 therein. The sides 20, 22 are also sealed along the edges thereof, while being left open at a mouth 26, oppositely disposed the central aperture 24, thereby defining a passage through the valve 16. The sides 20, 22 are preferably sealed together at their edges, and to the flange 18, by plastic welding, although any other suitable method may be used. Thus the configuration of the valve 16 is such that it has two modes of operation, as illustrated in figures 1 and 2 respectively. In figure 1, the valve 16 is shown in a closed state, in which nothing is being consumed/swallowed by the individual, and so the stomach 12 should be sealed. As the valve 16 is a mitral valve, the natural pressure within the stomach 12 forces the sides 20, 22 flat against one another, shutting the mouth 26, and therefore preventing reflux of stomach acid into the oesophagus 14.

Referring now to figure 2, once an item of food (not shown) or the like is swallowed, the item passes down the oesophagus 14 towards the entrance to the stomach 12, and reaches the device 10. Peristalsis within the oesophagus 14 forces the item through the central aperture 24, between the sides 20, 22, thereby forcing open the mouth 26 due to the flexible nature of the valve 16. Thus the item passes through the valve 16 safely into the stomach 12. Once passed, the mouth 26

is again forced closed by the pressure within the stomach 12, sealing the stomach 12 and preventing reflux. The flexibility of the valve 16 prevents any food items from becoming lodged therein, thus ensuring the safe operation of the device 10.

However, it will be appreciated that there are times when it may be necessary to allow pressure within the stomach 12 to be released, for example during vomiting or belching. The valve 16, together with the central aperture 24, is suitably flexible such that on a threshold pressure being reached within the stomach 12, the valve 16 is temporarily forced inside out, thereby enabling pressure to be vented into the oesophagus 14.

In order to affix the device 10 to the stomach 12, a layer of biocompatible adhesive (not shown) is provided on the upperside of the flange 18, facing the stomach 12, thereby providing a quick and effective means of securing the device 10 to the stomach 12. There are however a number of ways in which the device 10 could be located and secured in position within the stomach 12. One method would be to cut an incision in the stomach 12 from the exterior, and to then press the device 10 into place by hand, applying pressure until the adhesive of the flange 18 is suitably set. Alternatively, the device 10 could be sutured into place, possibly with dissolvable/biodegradable stitching or the like. The stomach 12 would then have to be stitched closed, in addition to the entry incision in the abdomen (not shown). However, such a

method is both time consuming, costly, and involves a significant recovery period. In addition, the conventional complications associated with such surgery, such as infection, rupturing of the incisions, etc., may arise.

Thus, referring to figures 3 and 4 of the accompanying drawings, the present invention also provides a method for inserting and securing the device 10 in place, which does not require any surgical incisions to be made.

The method essentially comprises inserting the device 10 down the oesophagus 14 and into the stomach 12, wherein the device 10 is drawn against the stomach 12, in order to affix same in place. Thus, in order to effect this method of insertion, a balloon 28 is provided, seated against the underside of the flange 18, with an inflating tube 30 being passed through the valve 16, and connected to the balloon 28. The inflating tube 30 is connected, in use, to a syringe 32 at the opposed end thereof, which may be operated to inflate the balloon 28, as will be described. It will however be appreciated that any other means may be provided in order to inflate the balloon 28. Prior to being connected to the syringe 32, the inflating tube 30 is passed first through a feed tube 40, formed from plastic or the like, which is itself located within an applicator tube 42, again being formed from plastic or the like, the feed tube 40 being slideable within the applicator tube 42.

An adhesive tube 34 is also provided, parallel to the inflating tube 30, which also passes through both the feed tube 40 and the applicator tube 42. The adhesive tube 34 is connected to a sleeve 36 projecting from the flange 18, which sleeve 36 is in fluid communication with an annular channel 38 on the flange 18. The annular channel 38 is provided with a plurality of minute apertures (not shown) on the upper side of the flange 18. Thus, in use, a suitable adhesive (not shown) may be pumped down the adhesive tube 34, around the annular flange 38, and seep out of the apertures (not shown), thereby providing a layer of adhesive on the flange 18, to enable the device 10 to be adhered in place, as will be described hereinafter.

Thus, referring to figure 3, in order to insert the device 10 into the stomach 12, the balloon 28, deflated, is located beneath the device 10, both of which are then furled into a cylindrical form, and pressed against the free end of the feed tube 40. The applicator tube 42 is then slid down over the device 10 and balloon 28, in order to enclose same and retain the device 10 and balloon 28 in this furled state. The feed tube 40 and applicator tube 42 are then passed down the oesophagus 14, until the end of applicator tube 42 reaches the stomach 12. At this point, the applicator tube 42 is held in place, and the feed tube 40 slid further, in the direction of Arrow A, thereby forcing the device 10 and balloon 28 out of the applicator tube 42 and into the stomach 12.

At this point, the balloon 28 is inflated, thereby causing the device 10 to unfurl, and assume the state as illustrated in figure 5. Once the balloon 28 is fully inflated, the adhesive (not shown) is pumped into the annular channel 38, and therefore seeps out onto the upper side of the flange 18. The adhesive is then left for approximately 30 seconds, in order to allow same to begin to cure, wherein the balloon 28 is drawn against the stomach 12, as illustrated in figure 4, by pulling on the inflating tube 30. This therefore presses the adhesive covered flange 18 against the stomach 12, the central aperture 24 being aligned with the oesophagus 14, the pressure being maintained until the adhesive is sufficiently cured to secure the device 10 in place.

The balloon 28 is then detached from the inflating tube 30 by means of a collar 44, which effects separation of the balloon 28 from the inflating tube 30 upon a threshold pressure being reached within the balloon 28, which in the embodiment illustrated, is achieved when the volume of the balloon 28 reaches approximately 500cc. The inflating tube 30 is then retracted, causing the balloon 28 to deflate, thereby dropping into the stomach 12 to harmlessly degrade. Alternatively, the balloon 28 may be withdrawn back through the oesophagus 14, in a deflated state, by any suitable means, for example a cannula (not shown) or the like. The feed tube 40, applicator tube 42, inflating tube 30 and adhesive tube 34 are then withdrawn from the oesophagus

14, leaving the device 10 secured in place within the stomach 12. The device 10 then remains secured in place for a pre-determined period of time, in order to allow the lower oesophageal sphincter muscle (not shown) to repair, or alternatively to be repaired by surgery or medication. It will however be appreciated that a more permanent form of the device 10 could be provided, in order to replace the functioning of a permanently damaged lower oesophageal sphincter muscle (not shown).

The present invention is not limited to the embodiment described herein, which may be amended or modified without departing from the scope of the present invention.

Document made available under the Patent Cooperation Treaty (PCT)

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